

## REMARKS

Claims 1-27 were subject to examination in the Office Action of March 18, 2003. Claims 1-4, 7, 9-11, 15, 16, 18-20, 22 and 26 have been amended herein and Claims 28-51 added. In the outstanding Office Action, the claims stand rejected for indefiniteness and/or anticipation. The individual rejections, as well as the amendments to the specification and claims, will be addressed below.

### I. Amendments to the Specification.

The specification has been amended to correct a typographical error in the incorrect spelling of the term "sulfate" as "sulphate."

The specification has also been amended to delete recitation of "sodium chloride" in the list of salts at page 5, lines 18-21. The inclusion of sodium chloride in this listing is incorrect as would be apparent to one in the relevant art, in particular, in view of the statement at page 1, lines 32-33, of the specification (*i.e.*, sodium chloride has undesirable corrosive effects rather than the beneficial effects described at page 5, lines 20-21).

### II. Amendments to the Claim Set.

Claims 1-4, 7, 9-11, 15, 16, 18-20, 22 and 26 have been amended and Claims 28-51 added. These claim amendments and new claims are supported by the application as filed and present no new matter.

**Claim 1** has been amended to recite a proper Markush format and to delete the word "nitrates" and the word "zinc." Applicants note for the record that the scope of the other recited salts has not been narrowed. Claim 1 has also been amended to remove reference to a gas flotation process, which has been moved to new Claim 40.

**Claims 2 and 4** have been amended to recite use of any of the salts of claim 1, rather than only sodium sulfate.

**Claim 3** has been amended to recite the "method" of Claim 2 to provide proper antecedent basis.

**Claim 7** has been amended to depend from new Claim 40 (reciting a gas flotation process) rather than Claim 1.

**Claim 9** has been amended to clarify the claim language without altering the scope of the claim.

**Claims 10 and 11** have been amended to recite a proper Markush group.

**Claim 15** has been amended to omit aeration.

**Claim 16** has been amended to clarify the claim language.

**Claim 18** has been amended to correct the claim dependency from Claim 14 to Claim 15.

**Claim 19** has been amended to depend from new Claim 46 and to clarify the claim language without narrowing the scope thereof.

**Claim 20** has been amended to depend from new Claim 47.

**Claim 22** has been amended to depend from Claim 18 rather than Claim 21.

**Claim 26** has been amended to remove the language regarding the presence of residual bleaching agent. Claim 26 has also been amended to depend from new Claim 47 and the term "sodium sulfate" has been amended to "salt" to provide proper antecedent basis.

**New Claims 28 and 29** recite that the encysted protozoa are *Eimeria* oocysts or oocysts from recited species of *Eimeria*, respectively. These claims are supported by the application as filed, for example, at page 9, lines 6-9.

**New Claim 30** is similar to Claim 1 except that it recites particular salts encompassed by Claim 1. This claim is supported by Claim 1 as filed and the application at page 5, lines 14-20.

**New Claim 31** specifically recites that the salt is sodium sulfate and new **Claim 32** specifically recites that the salt is magnesium sulfate. These claims are also supported by the application at page 5, lines 14-20.

**New Claims 33-37** are similar in scope to original Claims 2-6, except that Claims 33-37 ultimately depend from Claim 30 rather than Claim 1.

**New Claims 38 and 39** recite that the encysted protozoa are *Eimeria* oocysts or oocysts from recited species of *Eimeria*, respectively. These claims are supported by the application as filed, for example, at page 9, lines 6-9.

**New Claim 40** recites a gas flotation process. This claim is supported by original Claim 1.

**New Claim 41** recites a sporulation method comprising aeration. This claim is supported by Claim 15 as originally filed.

**New Claims 42 and 43** recite that the encysted protozoa are *Eimeria* oocysts or oocysts from recited species of *Eimeria*, respectively. These claims are supported by the application as filed, for example, at page 9, lines 6-9.

**New Claims 44 and 45** recite incubation times for sporulation of "up to about 72 hours" and "between about 40 and 72 hours," respectively. These claims are supported by the application at page 7, line 38 to page 8, line 1.

**New Claim 46** recites that the encysted protozoa are *Eimeria* oocysts, which is supported by the application as filed, for example, at page 9, lines 6-9.

**New Claim 47** recites that the oocysts are separated "by a salt flotation process." This claim is supported throughout the application as filed, for example, at page 5, lines 12-13.

**New Claim 48** recites specific salts encompassed by Claim 1. This claim is also supported by the application at page 5, lines 14-20.

**New Claim 49** specifically recites that the salt is sodium sulfate and new **Claim 50** specifically recites that the salt is magnesium sulfate. These claims are also supported by the application at page 5, lines 14-20.

**New Claim 51** recites that the bleaching agent is hydrogen peroxide, which is supported by the application at page 8, lines 28-29.

In view of the foregoing, Applicants submit that the amendments to the claims and the new claims presented above are supported by the application as filed, and respectfully request entry thereof.

**III. Section 112, paragraph 2.**

Claims 1-27 stand rejected under 35 U.S.C. §112, second paragraph on various grounds of indefiniteness. These rejections will be addressed individually below.

Claims 2-6 stand rejected as indefinite for lack of sufficient antecedent basis in Claim 2 for the term "the sodium sulphate" in line 3. Claim 2 has been amended to delete this claim language, thereby mooted this rejection.

Claim 3 further stands rejected as indefinite for reciting the "mixture" of Claim 2. Claim 3 has been amended to recite the "method" as suggested by the Examiner.

Claims 18-27 are rejected as indefinite on the basis that Claim 18 recites "sporulating the separated oocysts by the method of claim 14"; however, Claim 14 is not drawn to a sporulation method. This rejection has been addressed by amending Claim 18 to depend from Claim 15.

The Office Action further states that Claims 15-17 are indefinite for reciting the term "unwanted microbial growth," on the basis that the term "unwanted" is not defined. The term "unwanted microbial growth" is intended to indicate that the level of microorganisms other than the oocysts is reduced or eliminated. Such microorganisms include but are not limited to viruses, bacteria, fungi and other protozoans. This meaning of the phrase "unwanted microbial growth" would be clear to those skilled in the art based on the specification and the knowledge in the relevant art.

Finally, Claims 1-27 are rejected for indefiniteness on the basis that the claims recite methods "for the purification and recovery of encysted protozoa." As an initial matter, the Applicants respectfully note that only original Claims 1-14 recited "encysted protozoa." The remaining original claims (Claims 15-27) recite "oocysts."

The Office Action argues that the claims are indefinite on the basis that the "specification also does not define the metes and bounds of which protozoa are included, except for possible microorganisms listed in Fig. 2 or the statement on page 9 that the encysted protozoa 'can be' avian coccidial oocysts listed on lines 7-8."

Applicants submit that the claim terms "encysted protozoa" and "oocysts" would be sufficiently clear and definite to those skilled in the relevant art. The terms "encysted protozoa" and "oocysts" are intended broadly and have their understood meaning in the art; thus, the claims encompass all encysted protozoa/oocysts. It is known in the art that many protozoans go through an encysted life stage. In some protozoans, this encysted form is called an "oocyst." Examples of protozoans that produce an oocyst form include but are not limited to *Eimeria*, *Cryptosporidium*, *Toxoplasma*, *Plasmodia* and *Isospora*. *Giardia lamblia* is an example of an encysted protozoan that produces a cyst, but not an oocyst. Applicants are enclosing herewith a textbook chapter on protozoans of clinical importance (Bowman, Dwight D., Georgi's Parasitology for Veterinarians. 6<sup>th</sup> ed. Chapter 2: Protozoans. Philadelphia. W.B. Saunders, 1995. pp. 83-111). As evidenced by this representative text, there is extensive knowledge in the art regarding various species of protozoa and their life cycles and forms.

Further, as particular examples of encysted protozoa, the specification states at page 9, lines 14-15 that the methods of the invention can be used in the manufacture of other animal and human vaccines, including "waterborne protozoa such as *Cryptosporidium* and *Giardia lamblia*." In addition, in Figure 1B and at page 9, lines 25-26, the specification describes use of coccidial oocysts from a variety of species of *Eimeria*.

In summary, Applicants assert that the metes and bounds of the terms "encysted protozoa" and "oocysts" as used in the claims would be sufficiently clear.

The outstanding rejections under §112, second paragraph have been addressed by the foregoing remarks and claim amendments. Accordingly, Applicants request that the rejections on this basis be withdrawn.

#### **IV. Art Rejections.**

Claim 1 stands rejected under 35 U.S.C. § 102(b) as anticipated by each of O'Grady et al., U.S. Patent No. 4,544,548 (Davis et al.) and Fuller et

al. Applicants note with appreciation that Claims 2-27 are free of any art rejections. The rejections with respect to Claim 1 are addressed below.

The Office Action states that O'Grady et al. teaches a sodium nitrate flotation solution for separation of encysted protozoa. As an initial point, the Applicants note that O'Grady et al. concerns separation of hookworm eggs, not oocysts, from *Tricuris vulpis*, *Toxocara canis*, *Nematodirus spp.* and *Parascaris equorum*. Nonetheless, to expedite the prosecution of this application to allowance, Claim 1 has been amended to omit the term "nitrates," thereby obviating this rejection. O'Grady et al. does not disclose or suggest any of the other salts recited in Claim 1.

The Office Action further states that Davis et al. and Fuller et al. "teach a salt flotation process," thereby anticipating Claim 1. The Davis et al. patent specifically describes use of a sodium chloride solution for the separation of oocysts. As discussed in the present application, sodium chloride solutions are known in the art for purifying encysted protozoa, but have undesirable properties such as corrosive effects on equipment (see, e.g., specification at page 1, lines 32-33). In contrast, the salts recited by Claim 1 are less corrosive to process equipment than is sodium chloride (see, specification at page 5, lines 20-21). Davis et al. does not disclose salts other than sodium chloride and therefore does not anticipate the subject matter of Claim 1.

With respect to Fuller et al., this reference generically teaches "salt flotation" for purification of oocysts. Again, Applicants acknowledge that salt flotation was known in the art. However, Fuller et al. does not in any way disclose or suggest the salts recited by Claim 1 for purification of encysted protozoa. The subject matter of Claim 1 is therefore novel and nonobvious over the Fuller et al. reference as well.

In view of the foregoing, Applicants respectfully submit that the subject matter of Claim 1 is both novel and nonobvious over the cited references and request that the outstanding anticipation rejections be withdrawn.

Finally, in Point 14, the Office Action states that Claims 2-14 and 18-27 are objected to for depending from rejected Claim 1. In view of the foregoing


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discussion, Applicants submit that Claim 1 is in allowable form, and therefore the objection to Claims 2-14 and 18-27 should be withdrawn.

**V. Conclusion.**

The concerns of the Examiner having been addressed in full, Applicants respectfully request withdrawal of all outstanding rejections and the issuance of a Notice of Allowance forthwith. The Examiner is encouraged to address any questions regarding the foregoing to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,

  
Karen A. Magri  
Registration No. 41,965



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Vickie Diane Prior